REMARKS/ARGUMENTS

Claim Rejection

Claims 1-13 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. patent No. 6,669,663.

The Examiner is asked to note the terminal disclaimer (Form PTO/SB/26) and Preliminary Amendment the Applicant submitted to the U.S. Patent Office on April 6, 2004. *See* "Exhibit A" attached. Evidence of the U.S. Patent Office's receipt of Applicant's terminal disclaimer and Preliminary Amendment are attached, namely: (1) return receipt postcard stamped by the U.S. Patent Office on April 6, 2004; and (2) printout from the Transaction History obtained from the United States Patent and Trademark Office's Patent Application Information Retrieval database showing receipt on April 6, 2004. *See* "Exhibit B" attached.

Conclusion

In view of the foregoing, it is respectfully submitted that pending claims 14-206 are in condition for allowance. The Examiner is invited to contact the undersigned at the telephone number provided below, should it be deemed necessary to facilitate prosecution of the application.

Respectfully submitted,
BANNER & WITCOFF, LTD.

Dated: September 12, 2007

By: 

Charles W. Shifley
Registration No. 28,042
Direct Dial: (312) 463-5441

Banner & Witcoff, Ltd.
Ten South Wacker Drive
Suite 3000
Chicago, Illinois 60606
(312) 463-5000

Exhibit A

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 4576

Complete if Known	
Application Number	10/474,832
Filing Date	December 29, 2003
First Named Inventor	David L. Thompson
Examiner Name	
Art Unit	
Attorney Docket No.	011738.00214

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 19-0733

Deposit Account Name: Banner & Witcoff, LTD.

The Director is authorized to: *(check all that apply)*

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Raissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below		Fee Paid
Total Claims	193	-20 ** =	173	X	18	=	3114
Independent Claims	20	-3 ** =	17	X	86	=	1462
Multiple Dependent				X		=	0

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	88	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissua Independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 4576

***or number previously paid, if greater; For Reissues, see above*

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,330	2453	665	Petition to revive – unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) ____

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($) 0

SUBMITTED BY

				Complete (if applicable)	
Name (Print/Type)	Charles W. Shifley	Registration No. (Attorney/Agent)	28,042	Telephone	312-463-5000
Signature	Charles W. Shifley			Date	April 6, 2004

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

PTO/SB/21 (05-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/747,832
Filing Date	December 29, 2003
First Named Inventor	David L. Thompson
Art Unit	
Examiner Name	
Attorney Docket Number	011738.00214

Total Number of Pages in This Submission

ENCLOSURES *(check all that apply)*

- ☒ Fee Transmittal Form
- ☐ Fee Attached
- ☒ Amendment / Response
- ☐ After Final
- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
- ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below):* **Terminal disclaimer**

Remarks: **Being filed via Express Mail No.: EL 955623923 US**

The Commissioner is hereby authorized to charge any deficiencies in payment or credit any overpayment to our Deposit Account 19-0733.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Charles W. Shifley
Signature	Charles W. Shifley
Date	April 6, 2004

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name			
Signature		Date	

PTO/ SB/28 (05-03)
Approved for use through 4/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT

Docket Number (Optional)
11738.00214

In re Application of: David L. Thompson

Application No. 10/747,832

Filed: December 29, 2003

For: CLOSED LOOP MEDICAMENT PUMP

The owner*, Medtronic, Inc. of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 and 173, as presently shortened by any terminal disclaimer, of prior Patent No. 6,669,663. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the prior patent, as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☒ For submissions on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☐ The undersigned is an attorney of record.

Charles W. Shifley — April 6, 2004

Signature — Date

Charles W. Shifley

Typed or printed name

312-463-5000

Telephone Number

☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

*Certification under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:		Atty. Docket No.:	011738.00214
	David L. Thompson		
Serial No.:	10/747,832	Group Art Unit:	
Filed:	December 29, 2003	Examiner:	N/A
For:	CLOSED LOOP MEDICAMENT PUMP	Confirmation No.:	

PRELIMINARY AMENDMENT

Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

Prior to examination, please amend the application as follows:

In the Specification:

Background of the Invention:

Please add the previously omitted priority claim as paragraph one beginning at page 1:

-- This application claims priority to U.S. Application Ser. No. 09/302,593, filed April 30, 1999, issued on December 30, 2003 as U.S. Patent No. 6,669,663, which is incorporated herein by reference in its entirety. –

Amendments to the Claims are reflected in the Listing of Claims, which begins on page 2 of this paper.

Remarks/Arguments begin on page 53 of this paper.

Amendments to the Claims

Please amend the identified patent application by deleting the claims filed with the application and entering the following claims for examination. Please note the remarks below. Please also accept the enclosed Terminal Disclaimer to obviate any possible obviousness-type double patenting issue relative to U.S. Patent No. 6,669,663.

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-13: (**Cancelled**)

Claim 14. (New) A closed loop medicament pump system for a patient for sampling and determining the concentration of a substance of interest through the patient's skin and for determining and delivering a responsive dose of an appropriate medicament to the patient comprising:

an iontopheretic sensor module for sampling and detecting a concentration of a substance of interest through skin, wherein the sensor module comprises a sampling system and a concentration determining system;

a control system, responsive to the iontopheretic sensor module, for determining a response to the sampled and determined concentration of a substance of interest;

a sensor telemetry system for transmitting information regarding the response determined by the control system through the patient's body;

a pump telemetry system for receiving information regarding the response determined by the control system through the patient's body and for communicating the information to an implantable drug pump; and

an implantable drug pump, acting in response to the information communicated to the implantable drug pump from the pump telemetry system, to deliver a responsive dose of an appropriate medicament to the patient.

Claim 15. (New) A closed loop medicament pump system according to claim 14 wherein the sensor module is an external sensor.

Claim 16. (New) A closed loop medicament pump system according to claim 14 wherein the sensor module is disposable.

Claim 17. (New) A closed loop medicament pump system according to claim 14 wherein the sensor module is reusable.

Claim 18. (New) A closed loop medicament pump system according to claim 14 wherein the sensor module is attached to a flexible substrate.

Claim 19. (New) A closed loop medicament pump system according to claim 18 wherein the flexible substrate includes an adhesive to adhere the sensor module to skin of a patient.

Claim 20. (New) A closed loop medicament pump system according to claim 14 wherein the control system is a microprocessor.

Claim 21. (New) A closed loop medicament pump system as in claim 20, wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration.

Claim 22. (New) A closed loop medicament pump system as in claim 21, wherein the program further includes the step of generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament.

Claim 23. (New) A closed loop medicament pump system as in claim 21, wherein the program further includes the step, if the comparing step indicates the concentration does not exceed the predetermined limit, waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of

the substance of interest and comparing the information related to the concentration to information related to the predetermined limit.

Claim 24. (New) A closed loop medicament pump system as in claim 23, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program.

Claim 25. (New) A closed loop medicament pump system as in claim 23, in which the periodicity of the operation of the program, including the period of time for waiting, is programmable.

Claim 26. (New) A closed loop medicament pump system as in claim 21, in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command.

Claim 27. (New) A closed loop medicament pump system as in claim 21, in which the system, pump or medical device includes a patient command means and the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on patient command through the patient command means.

Claim 28. (New) A closed loop medicament pump system as in claim 20, in which the microprocessor further includes a memory with a look-up table for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes retrieving a value from the look-up table.

Claim 29. (New) A closed loop medicament pump system as in claim 20, in which the microprocessor further includes a memory with a formula for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes determining the dose according to the formula.

Claim 30. (New) A closed loop medicament pump system as in claim 29, in which the formula includes the variables of the determined concentration of the substance of interest and the patient's weight.

Claim 31. (New) A closed loop medicament pump system as in claim 20, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory.

Claim 32. (New) A closed loop medicament pump system as in claim 31, in which the information is stored in the memory with related time of the delivery of the responsive dose.

Claim 33. (New) A closed loop medicament pump system as in claim 31, in which the information is stored in the memory with related time of the delivery of the responsive dose and the memory keeps the information and time available for later uplink telemetry.

Claim 34. (New) A closed loop medicament pump system as in claim 33, further comprising uplink telemetry equipment.

Claim 35. (New) A closed loop medicament pump system as in claim 14, the drug pump acting in response to communication to the drug pump by body bus.

Claim 36. (New) A closed loop medicament pump system as in claim 14, the drug pump acting in response to communication to the drug pump by radio telemetry.

Claim 37. (New) A closed loop medicament pump system as in claim 14, further comprising an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer.

Claim 38. (New) A closed loop medicament pump system as in claim 14, further comprising an operatively connected battery.

Claim 39. (New) A closed loop medicament pump system, pump or medical device as in claim 38 wherein the battery is a flexible battery.

Claim 40. (New) A closed loop medicament pump system as in claim 14, in which the control system is located with the drug pump.

Claim 41. (New) A closed loop medicament pump system as in claim 14, in which the control system is located with the sensor module.

Claim 42. (New) A closed loop medicament pump system according to claim 14 wherein the substance of interest includes glucose and the sensor module samples and detects a concentration of the substance of interest including glucose.

Claim 43. (New) A closed loop medicament pump system according to claim 14 wherein the appropriate medicament is insulin, and the drug pump delivers insulin.

Claim 44. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest through the patient's skin and for determining and delivering a responsive dose of an appropriate medicament to the patient, wherein the substance of interest includes glucose and the medicament includes insulin, comprising:

a sensor module for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest;

an implantable drug pump for dispensing an appropriate amount of a medicament including insulin to the patient;

means for communicating information from the sensor module to the control system; and,

means for communicating information from the control system to the implantable drug pump.

Claim 45. (New) A closed loop medicament pump according to claim 44 wherein the sensor module is an external sensor.

Claim 46. (New) A closed loop medicament pump according to claim 44 wherein the sensor module is disposable.

Claim 47. (New) A closed loop medicament pump according to claim 44 wherein the sensor module is reusable.

Claim 48. (New) A closed loop medicament pump according to claim 44 wherein the sensor module is attached to a flexible substrate.

Claim 49. (New) A closed loop medicament pump according to claim 48 wherein the flexible substrate includes an adhesive to adhere the sensor module to skin of a patient.

Claim 50. (New) A closed loop medicament pump according to claim 44 wherein the control system is a microprocessor.

Claim 51. (New) A closed loop medicament pump as in claim 50, wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration.

Claim 52. (New) A closed loop medicament pump as in claim 51, wherein the program further includes the step of generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament.

Claim 53. (New) A closed loop medicament pump as in claim 51, wherein the program further includes the step, if the comparing step indicates the concentration does not exceed the predetermined limit, waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of the

substance of interest and comparing the information related to the concentration to information related to the predetermined limit.

Claim 54. (New) A closed loop medicament pump as in claim 53, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program.

Claim 55. (New) A closed loop medicament pump as in claim 53, in which the periodicity of the operation of the program, including the period of time for waiting, is programmable.

Claim 56. (New) A closed loop medicament pump as in claim 51, in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command.

Claim 57. (New) A closed loop medicament pump as in claim 51, in which the pump includes a patient command means and the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on patient command through the patient command means.

Claim 58. (New) A closed loop medicament pump as in claim 50, in which the microprocessor further includes a memory with a look-up table for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes retrieving a value from the look-up table.

Claim 59. (New) A closed loop medicament pump as in claim 50, in which the microprocessor further includes a memory with a formula for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes determining the dose according to the formula.

Claim 60. (New) A closed loop medicament pump as in claim 59, in which the formula includes the variables of the determined concentration of the substance of interest and the patient's weight.

Claim 61. (New) A closed loop medicament pump as in claim 50, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory.

Claim 62. (New) A closed loop medicament pump as in claim 61, in which the information is stored in the memory with related time of the delivery of the responsive dose.

Claim 63. (New) A closed loop medicament pump as in claim 61, in which the information is stored in the memory with related time of the delivery of the responsive dose and the memory keeps the information and time available for later uplink telemetry.

Claim 64. (New) A closed loop medicament pump as in claim 63, further comprising uplink telemetry equipment.

Claim 65. (New) A closed loop medicament pump as in claim 44, the drug pump acting in response to communication to the drug pump by body bus.

Claim 66. (New) A closed loop medicament pump as in claim 44, the drug pump acting in response to communication to the drug pump by radio telemetry.

Claim 67. (New) A closed loop medicament pump as in claim 44, further comprising an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer.

Claim 68. (New) A closed loop medicament pump as in claim 44, further comprising an operatively connected battery.

Claim 69. (New) A closed loop medicament pump as in claim 68 wherein the battery is a flexible battery.

Claim 70. (New) A closed loop medicament pump as in claim 44, in which the control system is located with the drug pump.

Claim 71. (New) A closed loop medicament pump as in claim 44, in which the control system is located with the sensor module.

Claim 72. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest and for determining and delivering a responsive dose of an appropriate medicament to the patient, wherein the substance of interest includes glucose and the medicament includes insulin, comprising:

a sensor for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest;

an implantable drug pump for dispensing an appropriate amount of a medicament including insulin to the patient;

a first communications system capable of communicating information, regarding the sensed concentration of a substance of interest in the patient, from the sensor to the control system; and,

a second communications system capable of communicating information, regarding the determined response to the determined concentration of the substance of interest, from the control system to the implantable drug pump.

Claim 73. (New) A closed loop medicament pump system according to claim 72 wherein the sensor module is an external sensor.

Claim 74. (New) A closed loop medicament pump according to claim 72 wherein the sensor module is disposable.

Claim 75. (New) A closed loop medicament pump according to claim 72 wherein the sensor module is reusable.

Claim 76. (New) A closed loop medicament pump according to claim 72 wherein the sensor module is attached to a flexible substrate.

Claim 77. (New) A closed loop medicament pump according to claim 76 wherein the flexible substrate includes an adhesive to adhere the sensor module to skin of a patient.

Claim 78. (New) A closed loop medicament pump according to claim 72 wherein the control system is a microprocessor.

Claim 79. (New) A closed loop medicament pump as in claim 78, wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration.

Claim 80. (New) A closed loop medicament pump as in claim 79, wherein the program further includes the step of generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament.

Claim 81. (New) A closed loop medicament pump as in claim 79, wherein the program further includes the step, if the comparing step indicates the concentration does not exceed the predetermined limit, waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit.

Claim 82. (New) A closed loop medicament pump as in claim 81, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program.

Claim 83. (New) A closed loop medicament pump as in claim 81, in which the periodicity of the operation of the program, including the period of time for waiting, is programmable.

Claim 84. (New) A closed loop medicament pump as in claim 79, in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command.

Claim 85. (New) A closed loop medicament pump as in claim 79, in which the system, pump or medical device includes a patient command means and the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on patient command through the patient command means.

Claim 86. (New) A closed loop medicament pump as in claim 78, in which the microprocessor further includes a memory with a look-up table for the responsive dose of

the appropriate medicament, and the step of determining the responsive dose includes retrieving a value from the look-up table.

Claim 87. (New) A closed loop medicament pump as in claim 78, in which the microprocessor further includes a memory with a formula for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes determining the dose according to the formula.

Claim 88. (New) A closed loop medicament pump as in claim 87, in which the formula includes the variables of the determined concentration of the substance of interest and the patient's weight.

Claim 89. (New) A closed loop medicament pump as in claim 78, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory.

Claim 90. (New) A closed loop medicament pump as in claim 89, in which the information is stored in the memory with related time of the delivery of the responsive dose.

Claim 91. (New) A closed loop medicament pump as in claim 89, in which the information is stored in the memory with related time of the delivery of the responsive dose and the memory keeps the information and time available for later uplink telemetry.

Claim 92. (New) A closed loop medicament pump as in claim 91, further comprising uplink telemetry equipment.

Claim 93. (New) A closed loop medicament pump as in claim 72, the drug pump acting in response to communication to the drug pump by body bus.

Claim 94. (New) A closed loop medicament pump as in claim 72, the drug pump acting in response to communication to the drug pump by radio telemetry.

Claim 95. (New) A closed loop medicament pump as in claim 72, further comprising an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer.

Claim 96. (New) A closed loop medicament pump as in claim 72, further comprising an operatively connected battery.

Claim 97. (New) A closed loop medicament pump as in claim 96 wherein the battery is a flexible battery.

Claim 98. (New) A closed loop medicament pump as in claim 72, in which the control system is located with the drug pump.

Claim 99. (New) A closed loop medicament pump as in claim 72, in which the control system is located with the sensor module.

Claim 100. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest and for determining and delivering a responsive dose of an appropriate medicament to the patient, wherein the substance of interest includes glucose and the medicament includes insulin, comprising:

an external, disposable, reusable sensor for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system including a microprocessor for determining an appropriate response to the determined concentration of the substance of interest, wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration, and generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament, and if the comparing step indicates the concentration does not exceed the predetermined limit,

waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program or programmed, and in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command, in which the microprocessor further includes one of either a memory with a look-up table or a formula for the responsive dose of the appropriate medicament or a memory , and the step of determining the responsive dose includes one of retrieving a value from the look-up table or determining the dose according to the formula;

an implantable drug pump for dispensing an appropriate amount of a medicament including insulin to the patient, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory with related time of the delivery of the responsive dose, and the memory keeps the information and time available for later uplink telemetry;

uplink telemetry equipment including an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer;

a first communications system capable of communicating information, regarding the sensed concentration of a substance of interest in the patient, from the sensor to the control system; and,

a second communications system capable of communicating information, regarding the determined response to the determined concentration of the substance of interest, from the control system to the implantable drug pump;

and an operatively connected battery.

Claim 101. (New) A closed loop medicament pump system as in claim 100, in which the control system is located with the drug pump.

Claim 102. (New) A closed loop medicament pump system as in claim 100, in which the control system is located with the sensor module.

Claim 103. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest and for determining and delivering a responsive dose of an appropriate medicament, wherein the substance of interest includes glucose and the medicament includes insulin, to the patient comprising:

a sensor module for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being integrally connected to the sensor module;

an implantable drug pump for dispensing an appropriate amount of a medicament including insulin to the patient; and

a telemetry system for communicating information from the control system to the implantable drug pump.

Claim 104. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest and for determining and delivering a responsive dose of an appropriate medicament, wherein the substance of interest includes glucose and the medicament includes insulin, to the patient comprising:

a sensor module for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being connected to the sensor module by a wire;

an implantable drug pump for dispensing an appropriate amount of a medicament including insulin to the patient; and

a telemetry system for communicating information from the control system to the implantable drug pump.

Claim 105. (New) A closed loop medical device for a patient for sampling and determining the concentration of a substance of interest including glucose in the patient and for taking an appropriate action in response thereto comprising:

a sensor module for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being integrally connected to the sensor module;

a medical device for taking an action appropriate to a concentration of interest in a patient; and

a telemetry system for communicating information from the control system to the medical device.

Claim 106. (New) A closed loop medical device for a patient for sampling and determining the concentration of a substance of interest including glucose in the patient and for taking an appropriate action in response thereto comprising:

a sensor module for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being connected to the sensor module by a wire;

a medical device for taking an action appropriate to a concentration of interest in a patient; and

a telemetry system for communicating information from the control system to the medical device.

Claim 107. (New) A closed loop medical device for a patient for determining the concentration of a substance of interest including glucose in the patient and for taking an appropriate action in response thereto comprising:

means for determining the concentration of a substance of interest including glucose in the patient;

means for determining an appropriate response to the determined concentration of the substance of interest;

a medical device for taking an action appropriate to a concentration of interest in a patient;

means for communicating information from the means for determining the concentration to the means for determining an appropriate response; and,

means for communicating information from the means for determining an appropriate response to the medical device.

Claim 108. (New) A closed loop medicament pump system for a patient for sampling and determining the concentration of a substance of interest from among the group of biological chemicals, enzymes, and hormones, through the patient's skin and for determining and delivering a responsive dose of an appropriate medicament to the patient comprising:

an iontopheretic sensor module for sampling and detecting a concentration of a substance of interest through skin;

a control system, responsive to the iontopheretic sensor module, for determining a response to the sampled and determined concentration of a substance of interest;

a sensor telemetry system for transmitting information regarding the response determined by the control system through the patient's body;

a pump telemetry system for receiving information regarding the response determined by the control system through the patient's body and for communicating the information to an implantable drug pump; and

an implantable drug pump, acting in response to the information communicated to the implantable drug pump from the pump telemetry system, to deliver a responsive dose of an appropriate medicament to the patient.

Claim 109. (New) A closed loop medicament pump system according to claim 108 wherein the sensor module is an external sensor.

Claim 110. (New) A closed loop medicament pump system according to claim 108 wherein the sensor module is disposable.

Claim 111. (New) A closed loop medicament pump system according to claim 108 wherein the sensor module is reusable.

Claim 112. (New) A closed loop medicament pump system according to claim 108 wherein the sensor module is attached to a flexible substrate.

Claim 113. (New) A closed loop medicament pump system according to claim 112 wherein the flexible substrate includes an adhesive to adhere the sensor module to skin of a patient.

Claim 114. (New) A closed loop medicament pump system according to claim 108 wherein the control system is a microprocessor.

Claim 115. (New) A closed loop medicament pump system as in claim 114, wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration.

Claim 116. (New) A closed loop medicament pump system as in claim 115, wherein the program further includes the step of generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament.

Claim 117. (New) A closed loop medicament pump system as in claim 115, wherein the program further includes the step, if the comparing step indicates the concentration

does not exceed the predetermined limit, waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit.

Claim 118. (New) A closed loop medicament pump system as in claim 117, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program.

Claim 119. (New) A closed loop medicament pump system as in claim 117, in which the periodicity of the operation of the program, including the period of time for waiting, is programmable.

Claim 120. (New) A closed loop medicament pump system, pump or medical device as in claim 115, in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command.

Claim 121. (New) A closed loop medicament pump system as in claim 115, in which the system, pump or medical device includes a patient command means and the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to

information related to the predetermined limit may be accomplished on patient command through the patient command means.

Claim 122. (New) A closed loop medicament pump system as in claim 114, in which the microprocessor further includes a memory with a look-up table for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes retrieving a value from the look-up table.

Claim 123. (New) A closed loop medicament pump system as in claim 114, in which the microprocessor further includes a memory with a formula for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes determining the dose according to the formula.

Claim 124. (New) A closed loop medicament pump system as in claim 123, in which the formula includes the variables of the determined concentration of the substance of interest and the patient's weight.

Claim 125. (New) A closed loop medicament pump system as in claim 114, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory.

Claim 126. (New) A closed loop medicament pump system as in claim 125, in which the information is stored in the memory with related time of the delivery of the responsive dose.

Claim 127. (New) A closed loop medicament pump system as in claim 125, in which the information is stored in the memory with related time of the delivery of the responsive dose and the memory keeps the information and time available for later uplink telemetry.

Claim 128. (New) A closed loop medicament pump system as in claim 127, further comprising uplink telemetry equipment.

Claim 129. (New) A closed loop medicament pump system as in claim 108, the drug pump acting in response to communication to the drug pump by body bus.

Claim 130. (New) A closed loop medicament pump system as in claim 108, the drug pump acting in response to communication to the drug pump by radio telemetry.

Claim 131. (New) A closed loop medicament pump system as in claim 108, further comprising an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer.

Claim 132. (New) A closed loop medicament pump system as in claim 108, further comprising an operatively connected battery.

Claim 133. (New) A closed loop medicament pump system as in claim 132 wherein the battery is a flexible battery.

Claim 134. (New) A closed loop medicament pump system as in claim 108, in which the control system is located with the drug pump.

Claim 135. (New) A closed loop medicament pump system as in claim 108, in which the control system is located with the sensor module.

Claim 136. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest from among the group of biological chemicals, enzymes, and hormones, through the patient's skin and for determining and delivering a responsive dose of an appropriate medicament to the patient comprising:

a sensor module for sampling and determining the concentration of a substance of interest in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest;

an implantable drug pump for dispensing an appropriate amount of a medicament to the patient;

means for communicating information from the sensor module to the control system; and,

means for communicating information from the control system to the implantable drug pump.

Claim 137. (New) A closed loop medicament pump according to claim 136 wherein the sensor module is an external sensor.

Claim 138. (New) A closed loop medicament pump according to claim 136 wherein the sensor module is disposable.

Claim 139. (New) A closed loop medicament pump according to claim 136 wherein the sensor module is reusable.

Claim 140. (New) A closed loop medicament pump according to claim 136 wherein the sensor module is attached to a flexible substrate.

Claim 141. (New) A closed loop medicament pump according to claim 140 wherein the flexible substrate includes an adhesive to adhere the sensor module to skin of a patient.

Claim 142. (New) A closed loop medicament pump according to claim 136 wherein the control system is a microprocessor.

Claim 143. (New) A closed loop medicament pump as in claim 142, wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration.

Claim 144. (New) A closed loop medicament pump as in claim 143, wherein the program further includes the step of generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament.

Claim 145. (New) A closed loop medicament pump as in claim 143, wherein the program further includes the step, if the comparing step indicates the concentration does not exceed the predetermined limit, waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of the

substance of interest and comparing the information related to the concentration to information related to the predetermined limit.

Claim 146. (New) A closed loop medicament pump as in claim 145, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program.

Claim 147. (New) A closed loop medicament pump as in claim 145, in which the periodicity of the operation of the program, including the period of time for waiting, is programmable.

Claim 148. (New) A closed loop medicament pump as in claim 143, in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command.

Claim 149. (New) A closed loop medicament pump as in claim 143, in which the system, pump or medical device includes a patient command means and the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on patient command through the patient command means.

Claim 150. (New) A closed loop medicament pump as in claim 142, in which the microprocessor further includes a memory with a look-up table for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes retrieving a value from the look-up table.

Claim 151. (New) A closed loop medicament pump as in claim 142, in which the microprocessor further includes a memory with a formula for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes determining the dose according to the formula.

Claim 152. (New) A closed loop medicament pump as in claim 151, in which the formula includes the variables of the determined concentration of the substance of interest and the patient's weight.

Claim 153. (New) A closed loop medicament pump as in claim 142, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory.

Claim 154. (New) A closed loop medicament pump as in claim 153, in which the information is stored in the memory with related time of the delivery of the responsive dose.

Claim 155. (New) A closed loop medicament pump as in claim 153, in which the information is stored in the memory with related time of the delivery of the responsive dose and the memory keeps the information and time available for later uplink telemetry.

Claim 156. (New) A closed loop medicament pump as in claim 155, further comprising uplink telemetry equipment.

Claim 157. (New) A closed loop medicament pump as in claim 136, the drug pump acting in response to communication to the drug pump by body bus.

Claim 158. (New) A closed loop medicament pump as in claim 136, the drug pump acting in response to communication to the drug pump by radio telemetry.

Claim 159. (New) A closed loop medicament pump as in claim 136, further comprising an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer.

Claim 160. (New) A closed loop medicament pump as in claim 136, further comprising an operatively connected battery.

Claim 161. (New) A closed loop medicament pump as in claim 160 wherein the battery is a flexible battery.

Claim 162. (New) A closed loop medicament pump as in claim 136, in which the control system is located with the drug pump.

Claim 163. (New) A closed loop medicament pump as in claim 136, in which the control system is located with the sensor module.

Claim 164. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest from among the group of biological chemicals, enzymes, and hormones, and for determining and delivering a responsive dose of an appropriate medicament to the patient comprising:

a sensor for sampling and determining the concentration of a substance of interest in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest;

an implantable drug pump for dispensing an appropriate amount of a medicament to the patient;

a first communications system capable of communicating information, regarding the sensed concentration of a substance of interest in the patient, from the sensor to the control system; and,

a second communications system capable of communicating information, regarding the determined response to the determined concentration of the substance of interest, from the control system to the implantable drug pump.

Claim 165. (New) A closed loop medicament pump according to claim 164wherein the sensor module is an external sensor.

Claim 166. (New) A closed loop medicament pump according to claim 164 wherein the sensor module is disposable.

Claim 167. (New) A closed loop medicament pump according to claim 164 wherein the sensor module is reusable.

Claim 168. (New) A closed loop medicament pump according to claim 164 wherein the sensor module is attached to a flexible substrate.

Claim 169. (New) A closed loop medicament pump according to claim 168 wherein the flexible substrate includes an adhesive to adhere the sensor module to skin of a patient.

Claim 170. (New) A closed loop medicament pump according to claim 164 wherein the control system is a microprocessor.

Claim 171. (New) A closed loop medicament pump as in claim 170, wherein the microprocessor operates a program including the steps of receiving information related to the concentration of the substance of interest, comparing the information related to the concentration to information related to a predetermined limit, and then, if the comparing step indicates the concentration exceeds the predetermined limit, determining the appropriate response to the determined concentration.

Claim 172. (New) A closed loop medicament pump as in claim 171, wherein the program further includes the step of generating information to cause the drug pump to deliver the responsive dose of the appropriate medicament.

Claim 173. (New) A closed loop medicament pump as in claim 171, wherein the program further includes the step, if the comparing step indicates the concentration does not exceed the predetermined limit, waiting for a period of time to expire before again operating the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit.

Claim 174. (New) A closed loop medicament pump as in claim 173, in which the periodicity of the operation of the program, including the period of time for waiting, may be present in the program.

Claim 175. (New) A closed loop medicament pump as in claim 173, in which the periodicity of the operation of the program, including the period of time for waiting, is programmable.

Claim 176. (New) A closed loop medicament pump as in claim 171, in which the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on command.

Claim 177. (New) A closed loop medicament pump as in claim 171, in which the system, pump or medical device includes a patient command means and the operation of the program steps of receiving information related to the concentration of the substance of interest and comparing the information related to the concentration to information related to the predetermined limit may be accomplished on patient command through the patient command means.

Claim 178. (New) A closed loop medicament pump as in claim 170, in which the microprocessor further includes a memory with a look-up table for the responsive dose of

the appropriate medicament, and the step of determining the responsive dose includes retrieving a value from the look-up table.

Claim 179. (New) A closed loop medicament pump as in claim 170, in which the microprocessor further includes a memory with a formula for the responsive dose of the appropriate medicament, and the step of determining the responsive dose includes determining the dose according to the formula.

Claim 180. (New) A closed loop medicament pump as in claim 179, in which the formula includes the variables of the determined concentration of the substance of interest and the patient's weight.

Claim 181. (New) A closed loop medicament pump as in claim 170, in which the drug pump includes memory, and the information communicated to the pump to cause the drug pump to deliver the responsive dose of the appropriate medicament is stored in the memory.

Claim 182. (New) A closed loop medicament pump as in claim 181, in which the information is stored in the memory with related time of the delivery of the responsive dose.

Claim 183. (New) A closed loop medicament pump as in claim 181, in which the information is stored in the memory with related time of the delivery of the responsive dose and the memory keeps the information and time available for later uplink telemetry.

Claim 184. (New) A closed loop medicament pump as in claim 183, further comprising uplink telemetry equipment.

Claim 185. (New) A closed loop medicament pump as in claim 164, the drug pump acting in response to communication to the drug pump by body bus.

Claim 186. (New) A closed loop medicament pump as in claim 164, the drug pump acting in response to communication to the drug pump by radio telemetry.

Claim 187. (New) A closed loop medicament pump as in claim 164, further comprising an operatively connected antenna which receives downlinked telemetry programming data transmitted by an external programmer.

Claim 188. (New) A closed loop medicament pump as in claim 164, further comprising an operatively connected battery.

Claim 189. (New) A closed loop medicament pump as in claim 188 wherein the battery is a flexible battery.

Claim 190. (New) A closed loop medicament pump as in claim 164, in which the control system is located with the drug pump.

Claim 191. (New) A closed loop medicament pump as in claim 164, in which the control system is located with the sensor module.

Claim 192. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest from among the group of biological chemicals, enzymes, and hormones, and for determining and delivering a responsive dose of an appropriate medicament to the patient comprising:

a sensor module for sampling and determining the concentration of a substance of interest in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being integrally connected to the sensor module;

an implantable drug pump for dispensing an appropriate amount of a medicament to the patient; and

a telemetry system for communicating information from the control system to the implantable drug pump.

Claim 193. (New) A closed loop medicament pump for a patient for sampling and determining the concentration of a substance of interest from among the group of biological chemicals, enzymes, and hormones, and for determining and delivering a responsive dose of an appropriate medicament to the patient comprising:

a sensor module for sampling and determining the concentration of a substance of interest in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being connected to the sensor module by a wire;

an implantable drug pump for dispensing an appropriate amount of a medicament to the patient; and

a telemetry system for communicating information from the control system to the implantable drug pump.

Claim 194. (New) A closed loop medical device for a patient for sampling and determining the concentration of a substance of interest in the patient from among the group of biological chemicals, enzymes, and hormones, and for taking an appropriate action in response thereto comprising:

a sensor module for sampling and determining the concentration of a substance of interest in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being integrally connected to the sensor module;

a medical device for taking an action appropriate to a concentration of interest in a patient; and

a telemetry system for communicating information from the control system to the medical device.

Claim 195. (New) A closed loop medical device for a patient for sampling and determining the concentration of a substance of interest in the patient from among the group of biological chemicals, enzymes, and hormones, and for taking an appropriate action in response thereto comprising:

a sensor module for sampling and determining the concentration of a substance of interest in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest, the control system being connected to the sensor module by a wire;

a medical device for taking an action appropriate to a concentration of interest in a patient; and

a telemetry system for communicating information from the control system to the medical device.

Claim 196. (New) A closed loop medical device for a patient for determining the concentration of a substance of interest in the patient from among the group of biological chemicals, enzymes, and hormones, and for taking an appropriate action in response thereto comprising:

means for determining the concentration of a substance of interest in the patient;

means for determining an appropriate response to the determined concentration of the substance of interest;

a medical device for taking an action appropriate to a concentration of interest in a patient;

means for communicating information from the means for determining the concentration to the means for determining an appropriate response; and,

means for communicating information from the means for determining an appropriate response to the medical device.

Claim 197. (New) A closed loop medical device as in claim 196 in which the sensor module or sensor or concentration determining means determines concentration of substances from among the group of drugs of Table 4 of U.S. Patent No. 5,730,714.

Claim 198. (New) A method of treating a medical condition in a patient comprising the steps of:

providing: a sensor module for sampling and determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response to the determined concentration of the substance of interest;

an implantable drug pump for dispensing an appropriate amount of a medicament to the patient;

means for communicating information from the sensor module to the control system; and,

means for communicating information from the control system to the implantable drug pump;

determining the concentration of a substance of interest including glucose;

comparing the determined concentration of the substance of interest to a predetermined limit;

determining an appropriate response to the determined concentration of the substance of interest;

communicating the determined appropriate response to the medicament pump.

Claim 199. (New) The method of claim 198 further comprising the step of infusing, if an appropriate response is determined to be to infuse medicament to a patient, medicament to the patient.

Claim 200. (New) The method of claim 199 further comprising the step of infusing, if an appropriate response is determined to be to infuse medicament to a patient, medicament including insulin to the patient.

Claim 201. (New) A method of treating a medical condition in a patient comprising the steps of: providing:

a sensor module for determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response the determined concentration of the substance of interest;

an implantable drug pump for dispensing an appropriate amount of a medicament to the patient;

means for communicating information from the sensor module to the control system; and,

means for communicating information from the control system to the implantable drug pump;

determining the concentration of a substance of interest;

comparing the determined concentration of the substance of interest to a predetermined limit;

determining an appropriate response to the determined concentration of the substance of interest;

taking the appropriate response by action by the drug pump.

Claim 202. (New) The method of claim 201 further comprising the step of infusing, if an appropriate response is determined to be to infuse medicament to a patient, medicament to the patient.

Claim 203. (New) The method of claim 201 further comprising the step of infusing, if an appropriate response is determined to be to infuse medicament to a patient, medicament including insulin to the patient.

Claim 204. (New) A method of treating a medical condition in a patient comprising the steps of: providing:

a sensor module for determining the concentration of a substance of interest including glucose in the patient;

a control system for determining an appropriate response the determined concentration of the substance of interest;

a medical device for taking an action appropriate to a concentration of interest in a patient;

means for communicating information from the sensor module to the control system; and,

means for communicating information from the control system to the medical device;

determining the concentration of a substance of interest;

comparing the determined concentration of the substance of interest to a predetermined limit;

determining an appropriate response by the medical device to the determined concentration of the substance of interest;

taking the appropriate response by action by the medical device.

Claim 205. (New) The method of claim 204 further comprising the step of infusing, if an appropriate response is determined to be to infuse medicament to a patient, medicament to the patient.

Claim 206. (New) The method of claim 205 further comprising the step of infusing, if an appropriate response is determined to be to infuse medicament to a patient, medicament including insulin to the patient.

REMARKS

The foregoing claims should be allowable on first Office Action. All the foregoing claims are comparable to the issued claims of U.S. Patent No. 6,669,663. None are of the same scope. With entry of the accompanying Terminal Disclaimer, the claims should be immediately allowable.

To better permit the Examiner to perceive the scope of the claims and their relationship to the issued claims of the '663 patent, the following is stated.

I. "Device" Claims

A. Iontopheretic Sensing Claims

Application claim 14 is '663 patent claim 1, which included iontopheretic sensing, with application claim 14 further including the additional limitation that the sensor module comprises a sampling system and a concentration determining system. A claim such as application claim 14 was not issued in the '663 patent because '663 patent claim 1 had no dependent claims.

Additional application claims 15 – 20, which are dependent on application claim 14, parallel patent claims 5-10, which were dependent on patent claim 2. Additional application claims 21 – 41 are directed to additional limitations taken from the specification. They depend from application claim 14 and its dependent claim 20. Additional application claims 42 and 43 direct themselves to the subject of application claim 14 with additional limitations directed to glucose detection and insulin delivery.

B. Glucose Detection and Insulin Delivery

Application claim 44 is patent claim 2, with additional limitations directed to glucose detection and insulin delivery. Application claims 45 – 50 parallel patent claims

5 – 10, with dependency on application claim 44. Application claims 51 – 71 parallel application claims 21 – 41. The patent claims did not expressly limit themselves to glucose detection or insulin delivery.

Application claim 72 is patent claim 13, with added limitations directed to glucose detection and insulin delivery. Application claims 73 – 78 parallel patent claims 5 – 10, with dependency on application claim 72. Application claims 79 - 99 parallel application claims 21-41. Applications claims 100 – 102 are highly detailed claims incorporating many of the limitations of application claims 73 –99, and the limitations of application claim 72.

Application claims 103 - 107 are patent claims 16 - 20, with added limitations directed to glucose detection and insulin delivery.

C. New Independent Claims and Their Dependent Claims

Application claims 108, 136, 164, 192, 193, 194, 195 and 196 are patent claims 1, 2, 13, 16, 17, 18, 19, and 20 with additional limitations directed to the substance of interest being from among the group of biological chemicals, enzymes, and hormones. The dependent claims from these claims also parallel the dependent application claims 15 – 43.

E. Method Claims

Application claims 198 – 206 are patent claims 11 – 12 and 14 – 15 and a few additional dependent claims with added limitations directed to glucose detection and insulin delivery.

CONCLUSION

All the claims now presented for examination are comparable to the issued claims of U.S. Patent No. 6,669,663. For all the same reasons that the claims of the '663 patent were allowable, the claims now presented are allowable. They are also allowable for all reasons associated with their additional limitations. The enclosed Terminal Disclaimer obviates any possible obviousness type double patenting rejection, and therefore, the claims should be allowed on first Office Action.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: April 6, 2004

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Exhibit B

☒ UTILITY ☐ DESIGN PATENT B&W Ref. 011738.00214 Date 4-06-2004

Serial/Patent No. 10/747,832 BOX _____ Attn/Sec. CWS/sls

Inventor David L. Thompson Client Medtronic Inc.

Title CLOSED LOOP MEDICAMENT PUMP

The following has been received in the U.S. Patent and Trademark Office on the date stamped hereon:

☒ Transmittal ☒ Fee Transmittal w/Auth. to Charge Deposit Account
☐ Nonpublication Request Under 35 USC 122(b)(2)(B)(i) PTO/SB/35
☐ Application Data Sheet (ADS) : ☐ Initial ☐ Supplemental
☐ _____ total pp Spec, including : # of Claims _____
(# of Independent claims _____); ☐ Abstract
☐ Drawings : ☐ Formal ☐ Informal
# of distinct sheets _____ ; Figs. _____
☐ Declaration/Power of Attorney : ☐ Executed ☐ Unexecuted
☐ Assignment w/Recordation Form Cover Sheet PTO-1595
☐ IDS ☐ PTO/SB/08A ☐ PTO/SB/42 ☐ References ☐ w/Fee
☒ Preliminary Amendment
☐ Priority Claim (Foreign or U.S. Provisional, B&W # _____)
Country Appl. # Date
☐ w/Foreign Priority Document(s)
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Date	Transaction Description
06-12-2007	Mail Non-Final Rejection
06-09-2007	Non-Final Rejection
04-08-2004	Information Disclosure Statement considered
12-01-2004	Information Disclosure Statement considered
09-05-2006	Miscellaneous Incoming Letter
02-08-2006	Paralegal TD Accepted
02-07-2006	IFW TSS Processing by Tech Center Complete
02-07-2006	Case Docketed to Examiner in GAU
04-06-2004	terminal disclaimer fee paid
12-01-2004	Information Disclosure Statement (IDS) Filed
12-01-2004	Information Disclosure Statement (IDS) Filed
02-22-2005	Reference capture on IDS
04-08-2004	Information Disclosure Statement (IDS) Filed
04-08-2004	Information Disclosure Statement (IDS) Filed
04-06-2004	Preliminary Amendment
04-23-2004	Application Return from OIPE
04-23-2004	Application Return TO OIPE
04-22-2004	Application Dispatched from OIPE
04-23-2004	Application Is Now Complete
04-06-2004	Workflow incoming amendment IFW
02-25-2004	Cleared by OIPE CSR
01-16-2004	IFW Scan & PACR Auto Security Review
12-29-2003	Initial Exam Team nn

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